K024377

JUL 2 1 2003

510(k) Summary

Submitter's Name:	Kalaco Scientific, Inc.
Submitter's Address:	6514 N. 85th Place, Scottsdale, AZ 85250-5742
Submitter's Telephone:	(480) 948-9209
Contact Name:	Raymond R. Wallage
Date Summary was Prepared:	December 25, 2002
Trade or Proprietary Name:	Transcranial Electrotherapy Stimulator-A (TESA)
Common or Usual Name:	CES
Classification Name:	Stimulator, Cranial Electrotherapy (21 CFR 882. 5800)

Predicate Devices:

Device Name	510(k) Number
Alpha-Stim CS	K903014
Liss Cranial Stimulator, SBL202-B	K903654
HealthPax HP-1	K883812

Description of the Device and Summary of the Technological Characteristics:

The TESA is a transcranial electrotherapy stimulation device. Three electrodes are applied, one to the forehead and one behind each ear. TESA delivers low amplitude AC current for a desired time of 0 to 99:59 minutes. Treatment can be stopped by pressing the "current off" button. Either the operator or patient may press this button at any time. During treatment, peak current amplitude can be adjusted over the available range of 0 – 4 mA. Treatment parameters are monitored and controlled by a built in microprocessor. The display on the front of TESA indicates remaining treatment time and shows the current setting.

During treatment, a modulated high frequency square wave is delivered to the patient electrodes. The amplitude and duration of the positive and negative going portions of this waveform have been carefully designed to deliver no DC component. Moreover, the electrodes are AC coupled to the patient to insure no DC component in the event of device failure.

Additional safety features of the TESA device include rapid measurement of electrode impedance to insure good electrode contact and to maintain controlled current output over changing load conditions (e.g. when electrode contact changes). Detection of poor electrode contact causes the device to stop treatment and illuminate an electrode fault LED. Further treatment is blocked until electrode/skin impedance is restored to nominal range.

Indications for Use:

Treatment with the TESA device is intended to reduce the symptoms of depression, anxiety and insomnia.

The TESA device is intended for use by or on the order of a licensed health care practitioner. A trained technician will administer actual treatment.

Substantial Equivalence:

The TESA device uses a proprietary stimulation waveform, but the current amplitude and frequencies are similar to predicate devices such as the Alpha-Stim CS.

Testing:

Various tests of the hardware and software have been performed to verify that the device works as described in this document. Verification procedures with pass/fail criteria were developed to ensure that the product met all the specified requirements. As part of this verification, a certified body will be used to determine that the device conforms to the recognized safety standards listed below. The device will not be marketed until it has been tested and complies with the standards.

UL2601-1
IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60601-2-10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Kalaco Scientific, Inc.
c/o Grace Bartoo, Ph.D., RAC
Vice President Regulatory and Clinical Affairs
Instrumentation for Science and Medicine, Inc.
131 Glenn Way, Suite 7
San Carlos, California 94070

Re: K024377
Trade/Device Name: Transcranial Electrotherapy Stimulator-A, Model TESA-1
Regulation Number: 21 CFR 882.5800
Regulation Name: Cranial Electrotherapy Stimulator
Regulatory Class: Class III
Product Code: JXK
Dated: Undated
Received: April 22, 2003

Dear Dr. Bartoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D Indications for Use Statement

Ver/ 3 – 4/24/96

Applicant: Kalaco Scientific, Inc.

510(k) Number (if known): K024377

Device Name: TESA

Indications For Use:

Treatment with the TESA device is intended to reduce the symptoms of depression, anxiety and insomnia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024377

Prescription Use ✓ per 21 CFR 801.109

Over the Counter Use _____